SEP 2 3 2011

K112122

GE Healthcare

510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	July 21, 2011
Submitter:	GE Healthcare 9900 Innovation Dr Wauwatosa, WI 53226
Primary Contact Person:	Bryan Behn Regulatory Affairs Manager GE Healthcare T:(414)721-4214 F:(414)918-8275
Secondary Contact Person:	Yalan Wu Regulatory Affairs Manager GE Healthcare T: +86 510 8527 8652 F: +86 510 8522 7347
Device: Trade Name:	Venue 40
Common/Usual Name:	Venue 40
Classification Names:	Class II
Product Code:	Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Predicate Device(s):	Venue 40 - K102113 LOGIQ i/e & Vivid e - K102256 Logiq P5 - K060993
Device Description:	The Venue 40 device is a compact and extremely portable ultrasound system consisting of a hand-carried console with the ability to dock it with a Docking station or mobile Docking cart. The primary means of control is a small number of dedicated push buttons and graphical user interface implemented by a touch sensitive screen over the color LCD display providing additional command input and keyboard entry. It utilizes interchangeable electronic-array transducers operating B, Color and Power Doppler, M modes with digital acquisition, processing and display capability operating under a Linux OS. Powered by an integrated battery or from a separate power supply/charger in the

docking station or docking cart, the Venue 40 is used primarily where portability, size and convenience are essential.

Intended Use: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculoskeletal Conventional & Superficial; Transvaginal; Intraoperative (abdominal, thoracic and peripheral); Thoracic/Pleural for motion and fluid detection and imaging guidance of interventional procedures.

Technology: The Venue 40 employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

The Venue 40 and its applications comply with voluntary standards as detailed in Section 9, 11 and 17 of this premarket submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Transducer material and other patient contact materials such as needle guidance kits are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Venue 40, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Venue 40 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Mr. Bryan Behn
Regulatory Affairs Manager
GE Healthcare
9900 Innovation Dr.
WAUWATOSA WI 53226

SEP 2 3 2011

Re: K112122
Trade/Device Name: Venue 40
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN
Dated: July 21, 2011
Received: August 2, 2011

Dear Mr. Behn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Venue 40, as described in your premarket notification:

Transducer Model Number

12L-SC
3S-SC
4C-SC
L8-18i-SC
E8CS-SC

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely Yours,

Mary S. Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known): K112122

Device Name: Venue 40

Indications for Use:

The Venue 40 is intended for ultrasound imaging, measurement and analysis of the human body for multiple clinical applications including: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Musculoskeletal Conventional & Superficial; Transvaginal; Intraoperative (abdominal, thoracic and peripheral); Thoracic/Pleural for motion and fluid detection and imaging guidance of interventional procedures.

Prescription Use_X___ AND/OR Over-The-Counter Use_N/A_
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K112122

Diagnostic Ultrasound Indications for Use Form

GE Venue 40 Ultrasound

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation											
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse*	Elasto-graphy	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power					
Ophthalmic												
Fetal/OB	P	P			P		P	P	P			
Abdominal[1]	P	P			P		P	P	P			
Pediatric	P	P			P		P	P	P			
Small Organ (specify)[2]	P	P			P		P	P	P			
Neonatal Cephalic	P	P			P		P	P	P			
Adult Cephalic	P	P			P		P	P	P			
Cardiac[3]	P	P			P		P	P	P			
Peripheral Vascular	P	P			P		P	P	P			
Musculo-skeletal Conventional	P	P			P		P	P	P			
Musculo-skeletal Superficial	P	P			P		P	P	P			
Thoracic/Pleural (specify)[4]	P	P			P		P	P	P			
Other (specify)												
Exam Type, Means of Access												
Transcranial	P	P			P		P	P	P			
Transorbital												
Transesophageal												
Transrectal												
Transvaginal	N	N			N		N	N	N			
Intraoperative (specify)[5]	P	P			P		P	P	P			
Intraoperative Neurological												
Intravascular/Intraluminal												
Intracardiac												
Laparoscopic												
Interventional Guidance												
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P			
Vascular Access (IV, PICC)	P	P			P		P	P	P			
Nonvascular (specify)[6]	P	P			P		P	P	P			
Brachytherapy												

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] For detection of fluid and pleural motion/sliding;
[5] Intraoperative includes abdominal, thoracic and peripheral;
[6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block;
[*] Combined modes are color/power Doppler with B-mode

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112122

Diagnostic Ultrasound Indications for Use Form

GE Venue 40 with 12L-SC Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation											
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse*	Elasto-graphy	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power					
Ophthalmic												
Fetal/OB												
Abdominal[1]	P	P			P		P	P	P			
Pediatric	P	P			P		P	P	P			
Small Organ (specify)[2]	P	P			P		P	P	P			
Neonatal Cephalic	P	P			P		P	P	P			
Adult Cephalic												
Cardiac[3]												
Peripheral Vascular	P	P			P		P	P	P			
Musculo-skeletal Conventional	P	P			P		P	P	P			
Musculo-skeletal Superficial	P	P			P		P	P	P			
Thoracic/Pleural (specify)[4]	P	P			P		P	P	P			
Other (specify)												
Exam Type, Means of Access												
Transcranial												
Transorbital												
Transesophageal												
Transrectal												
Transvaginal												
Intraoperative (specify)[5]	P	P			P		P	P	P			
Intraoperative Neurological												
Intravascular/Intraluminal												
Intracardiac												
Laparoscopic												
Interventional Guidance												
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P			
Vascular Access (IV, PICC)	P	P			P		P	P	P			
Nonvascular (specify)[6]	P	P			P		P	P	P			
Brachytherapy												

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes; thyroid;
[3] Cardiac is Adult and Pediatric;
[4] For detection of fluid and pleural motion/sliding;
[5] Intraoperative includes abdominal, thoracic and peripheral;
[6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block
[*] Combined modes are color/power Doppler with B-mode

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112122

Diagnostic Ultrasound Indications for Use Form

GE Venue 40 with 3S-SC Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation												
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse*	Elasto-graphy	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power					
Ophthalmic												
Fetal/OB	P	P			P		P	P	P			
Abdominal[1]	P	P			P		P	P	P			
Pediatric	P	P			P		P	P	P			
Small Organ (specify)[2]												
Neonatal Cephalic	P	P			P		P	P	P			
Adult Cephalic	P	P			P		P	P	P			
Cardiac[3]	P	P			P		P	P	P			
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Thoracic/Pleural (specify)[4]	P	P			P		P	P	P			
Other (specify)												
Exam Type, Means of Access												
Transcranial												
Transorbital												
Transesophageal												
Transrectal												
Transvaginal												
Intraoperative (specify)[5]	P	P			P		P	P	P			
Intraoperative Neurological												
Intravascular/Intraluminal												
Intracardiac												
Laparoscopic												
Interventional Guidance												
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P			
Vascular Access (IV, PICC)												
Nonvascular (specify)[6]												
Brachytherapy												

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] For detection of fluid and pleural motion/sliding;
[5] Intraoperative includes abdominal, thoracic and peripheral;
[6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block
[*] Combined modes are color/power Doppler with B-mode

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Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112122

Diagnostic Ultrasound Indications for Use Form

GE Venue 40 with 4C-SC Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation												
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse*	Elasto-graphy	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power					
Ophthalmic												
Fetal/OB	P	P			P		P	P	P			
Abdominal[1]	P	P			P		P	P	P			
Pediatric	P	P			P		P	P	P			
Small Organ (specify)[2]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac[3]												
Peripheral Vascular												
Musculo-skeletal Conventional	P	P			P		P	P	P			
Musculo-skeletal Superficial												
Thoracic/Pleural (specify)[4]	P	P			P		P	P	P			
Other (specify)												
Exam Type, Means of Access												
Transcranial												
Transorbital												
Transesophageal												
Transrectal												
Transvaginal												
Intraoperative (specify)[5]	P	P			P		P	P	P			
Intraoperative Neurological												
Intravascular/Intraluminal												
Intracardiac												
Laparoscopic												
Interventional Guidance												
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P			
Vascular Access (IV, PICC)												
Nonvascular (specify)[6]	P	P			P		P	P	P			
Brachytherapy												

N = new indication; P = previously cleared by FDA

Notes: [1] Abdominal includes GYN and Urological;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac is Adult and Pediatric;
[4] For detection of fluid and pleural motion/sliding;
[5] Intraoperative includes abdominal, thoracic and peripheral;
[6] Nonvascular is image guidance for freehand needle/catheter placement, including nerve block
[*] Combined modes are color/power Doppler with B-mode

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112122

Diagnostic Ultrasound Indications for Use Form

GE Venue 40 with L8-18i-SC Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation											
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse*	Elasto-graphy	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power					
Ophthalmic												
Fetal/OB												
Abdominal[1]	P	P			P		P	P	P			
Pediatric	P	P			P		P	P	P			
Small Organ (specify)[2]	P	P			P		P	P	P			
Neonatal Cephalic	P	P			P		P	P	P			
Adult Cephalic												
Cardiac[3]												
Peripheral Vascular	P	P			P		P	P	P			
Musculo-skeletal Conventional	P	P			P		P	P	P			
Musculo-skeletal Superficial	P	P			P		P	P	P			
Thoracic/Pleural (specify)[4]	P	P			P		P	P	P			
Other (specify)												
Exam Type, Means of Access												
Transcranial												
Transorbital												
Transesophageal												
Transrectal												
Transvaginal												
Intraoperative (specify)[5]	P	P			P		P	P	P			
Intraoperative Neurological												
Intravascular/Intraluminal												
Intracardiac												
Laparoscopic												
Interventional Guidance												
Tissue Biopsy/Fluid Drainage	P	P			P		P	P	P			
Vascular Access (IV, PICC)	P	P			P		P	P	P			
Nonvascular (specify)[6]	P	P			P		P	P	P			
Brachytherapy												

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Notes: [1] Abdominal includes GYN and Urological;
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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use (Per 21 CFR 801.109)

Mary S Pastel

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112122

Diagnostic Ultrasound Indications for Use Form

GE Venue 40 with E8CS-SC Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation											
			Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse	Elasto-graphy	Other
Anatomy/Region of Interest	B	M	PW	CW	Color	Color M	Power					
Ophthalmic												
Fetal/OB	N	N			N		N	N	N			
Abdominal[1]	N	N			N		N	N	N			
Pediatric												
Small Organ (specify)[2]												
Neonatal Cephalic												
Adult Cephalic												
Cardiac[3]												
Peripheral Vascular												
Musculo-skeletal Conventional												
Musculo-skeletal Superficial												
Thoracic/Pleural (specify)[4]												
Other (specify)												
Exam Type, Means of Access												
Transcranial												
Transorbital												
Transesophageal												
Transrectal												
Transvaginal	N	N			N		N	N	N			
Intraoperative (specify)[5]												
Intraoperative Neurological												
Intravascular/Intraluminal												
Intracardiac												
Laparoscopic												
Interventional Guidance												
Tissue Biopsy/Fluid Drainage												
Vascular Access (IV, PICC)												
Nonvascular (specify)[6]												
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